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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,382	06/15/2005	Masahiro Toda	TODA	1639

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BARNES & THORNBURG LLP
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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,382	TODA ET AL.	
	Examiner	Art Unit	
	Meera Natarajan Ph.D.	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-5, drawn to a method for screening for a tumor suppressor gene or an oncogene.

II. Claim 6, 12, and 13, drawn to a method for diagnosing a cancer.

III. Claim 7, 14, and 15 drawn to a diagnostic agent for a cancer.

IV. Claim 8, 10, 12, and 13 drawn to a therapeutic method for a cancer, comprising either expressing in a cancer cell the tumor suppressor gene in a cancer such as human glioma, or administering to a cancer patient at least one of a gene product of said tumor suppressor gene, a methyltransferase inhibitor, and a histone deacetylase inhibitor or an expression inhibitor of the oncogene or gene product of the oncogene.

V. Claims 9, 11, 14, and 15 drawn to a therapeutic agent for a cancer.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the following reasons: The technical feature recited

in claim 1 is a method for screening for a tumor suppressor gene or an oncogene by measuring the degree of methylation of cytosine residues in a CpG island derived from a human glioma or a human glioma cell line. In view of this Dong et al. (J. Neuropath. Exp. Neurol. 2001) reads on the claim. Dong et al. teaches hypermethylation of CpG islands at the gene promoter regions of several tumor-related genes is involved in the carcinogenesis of glioma tumors. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

3. The methods of Groups I, II, and IV differ in the method objectives, method steps and parameters and in the reagents used. Group I recites a method for screening for a tumor suppressor gene or an oncogene, Group II recites a method for diagnosing a cancer, and Group IV recites a therapeutic method for a cancer. The method of screening in Group I only involves measuring the degree of methylation whereas Group II, a method for diagnosing, involves measuring not only degree of methylation but gene mutations and expression. In addition, the methods of Group I and II (screening and diagnosing) do not involve administering an agent to a cancer patient such as in Group IV. Examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Groups I, II, and IV are separate and distinct in having different method steps and different endpoints and are patentably distinct.

4. Groups III and V represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have

different modes of operation, different functions and different effects. The diagnostic agent of Group III and the therapeutic agent of Group V are different in the manner that they are used in materially different methods. The therapeutic agents of Group V comprise being administered to a cancer patient whereas the therapeutic agents of Group III do not. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the Groups III and V are patentably distinct.

5. Groups [III and II] and [V and IV] are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the diagnostic or therapeutic agents claimed in Groups III and V can be used in materially different processes than the diagnosing or therapeutic methods claimed in Groups II and IV. The products claimed can be used in processes that do not involve cancer diagnosing or treatment, but rather functional characteristics of a tumor or tumor cell line such as, proliferative, migratory, apoptotic, and/or invasive.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If any of Groups I-V is elected, applicant must elect a "screening for" species:

Screening for (claim 1-5):

a) tumor suppressor gene

b) oncogene

If species (a) is chosen above a further election of tumor suppressor gene species must be elected:

Tumor suppressor (claims 3):

1) RFX1

2) BGT-1

If species (b) is chosen above a further election of Oncogene species must be elected:

Oncogene (claim 5):

3) HOXD1

4) HOXD3

5) HOXD4

6) HOXD8

7) HOXD9

8) HOXD13

9) HOXA9

10) HOXB9

11) HOXC9

If Group II or III is elected, applicant must elect a "measurement of" species:

Measurement of (claim 6 and 7):

a) degree of methylation

b) presence of gene mutation

c) absence of gene mutation

d) gene expression

e) protein expression of the tumor suppressor gene

f) protein expression of the oncogene

If Group IV or V is elected, applicant must elect a "therapeutic agent" species and a "therapeutic methods and agents" species:

Therapeutic agent (claim 8 and 9):

a) tumor suppressor gene

b) gene product of tumor suppressor gene

c) methyltransferase inhibitor

d) histone deacetylase inhibitor

Therapeutic methods and agents (claims 8-11):

a) express tumor suppressor gene

b) administer tumor suppressor gene product

c) administer methyltransferase inhibitor

d) administer histone deacetylase inhibitor

e) administer expression inhibitor of oncogene

f) administer peptide/protein that binds expression inhibitor of oncogene

g) administer peptide/protein that binds gene product of oncogene

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. The claims are deemed to correspond to the species listed above in the following manner: All of the claims involve multiple species; no claim is drawn to a single species. All claims are generic.

10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The difference between oncogenes and tumor suppressor genes is that oncogenes result from the *activation* (turning on) of proto-oncogenes, but tumor suppressor genes cause cancer when they are *inactivated* (turned off). The measurement species are independent and distinct because they have different method steps, parameters, and reagents. The therapeutic methods and agents species are independent and distinct because they have different modes of operation, functions, and effects.

11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan Ph.D. whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

ZACHARIAH LUCAS
PATENT EXAMINER